

No. COX 01-007  
Feb 09, 2001

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**Bulletin for VIOXX®:  
FDA Arthritis Advisory Committee Meeting for VIOXX®**

**TO:**

All field personnel with responsibility for VIOXX®  
National Account Executives  
and Customer Managers (All Segments)

Action Required  
Background Information

***DO NOT INITIATE DISCUSSIONS ON THE FDA ARTHRITIS ADVISORY COMMITTEE (ADVISORY COMMITTEE) REVIEW OR THE RESULTS OF THE VIOXX® GI OUTCOMES RESEARCH (VIGOR) STUDY. YOU MAY RESPOND TO CUSTOMER INQUIRIES ONLY AS OUTLINED BELOW.***

**Introduction:**

As previously communicated in June 2000, Merck submitted a supplemental NDA for VIOXX based upon the VIOXX GI Outcomes Research study (VIGOR). In this study, VIOXX 50mg daily significantly reduced the risk of serious gastrointestinal side effects by 54% vs. naproxen 1000mg daily. On Thursday, Feb 8, Merck and the FDA reviewed the study with the FDA's Arthritis Advisory Committee.

The purpose of this bulletin is to provide you with important, updated background information based on the results of this meeting and actions required by you.

**Action Required:**

1. Stay focused on the EFFICACY messages for VIOXX
2. Utilize the PIR system to respond to unsolicited physician inquiries
3. Review the updated background Q&A
4. Review the updated obstacles and responses for your physicians
5. Do not initiate discussions or respond to questions, except as outlined below

**Stay Focused on Efficacy**

It is critical that we remain focused on the 1S HI NSAID and HI COXIB messages for VIOXX with our targeted physicians. As discussed at your 1S District Meetings, both the OA efficacy data and the new acute pain narcotic efficacy data for VIOXX will continue to solidify the efficacy perception of VIOXX. Use the new core visual aid for VIOXX and the

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PROTECTIVE ORDER IN  
ABRUSLEY V. MERCK, et al.  
(02-0196 W.D. La.)



MRK-ABR 0017219

OA Efficacy Stock Bottle Challenge program to challenge physicians to gain experience with the 24 hour efficacy of VIOXX.

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#### Physician Inquiries:

In response to unsolicited requests for information regarding VIGOR, Medical Services will make a personalized, faxable PIR available for your customers within 24 hours. In addition, for those customers who request additional information, a separate, more comprehensive PIR packet can be Federal Expressed within 2 days.

Medical Services has made arrangements to extend the hours for the PIR hotline. Representatives should submit unsolicited PIR requests by either telephone or fax options from 2/9 through 2/23 by calling the PIR hotline 800MERCK66 (800-637-2566) during extended hours of 8:30 am to 6:30pm ET. During these hours, a staff member will verbally request the following information from you to process the PIR request from the HCP. [After this time, the usual method options of INSIGHT, PIR hotline (800MERCK 66 -- hours: 8:30 -- 4:30pm ET) and fax can be followed].

#### Faxable PIR Instructions:

- Your name, field title and RDT
- The requesting HCP's full name and professional degree
- HCP's full mailing address
- HCP's phone number
- HCP's FAX number
- Provide the question(s) asked by the HCP.

PIR Requests may also be sent to Medical Services from 4:30 pm -- 8:30am ET by leaving a voice message at 800MERCK66. The information as listed above should be provided in your voice message to Medical Services staff. Additionally, PIR requests may be submitted to Medical Services in writing by sending a fax to 800MERCK66. The information listed above should be included on your fax to Medical Services.

#### In Summary:

- If requested, a summary of the PIR will be faxed within 24 hours of receiving the request.
- If the physician requests more comprehensive information on the VIGOR study, you may request the comprehensive PIR. This will be sent via Fed'EX within 2 days.
- Transition your discussion to the current strategy and messages for VIOXX®
- Do not proactively discuss the Advisory Committee Meeting or VIGOR. Respond to questions about the study by requesting a PIR and in accordance with the obstacle-handling guide.

#### Updated Q&A Guide:

This is background information only